

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

HAVERHILL RETIREMENT SYSTEM,
Derivatively on Behalf of The Medicines
Company,

Plaintiff,

v.

WILLIAM W. CROUSE, ALEXANDER J.
DENNER, FREDRIC N. ESHELMAN, JOHN
C. KELLY, HIROAKI SHIGETA, MELVIN
K. SPIGELMAN, and ROBERT G. SAVAGE,

Defendants,

and

THE MEDICINES COMPANY, a Delaware
Corporation,

Nominal Defendant.

Case No. _____

VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiff Haverhill Retirement System (“Haverhill” or “Plaintiff”) brings this action derivatively on behalf of The Medicines Company (“Medicines” or the “Company”) against the Individual Defendants who are the majority of the current members of the Medicines Board of Directors (the “Board”). The allegations herein are based on Plaintiff’s personal knowledge with respect to its own actions, and on information and belief (including investigation of counsel and a review of Medicines’ Board and committee presentations and minutes pursuant to an 8 Del. C. §220 books and records demand) as to all other matters alleged.

SUMMARY OF ACTION

1. Medicines, a Delaware corporation, is a publicly owned company with headquarters in Parsippany, New Jersey, whose primary focus is to research and produce biopharmaceutical products in three critical therapeutic areas: serious infectious disease care, cardiovascular care, and surgery and perioperative care.

2. One of Medicines' most promising products, cangrelor, was an antiplatelet agent intended to prevent dangerous blood clotting in patients with coronary artery disease. Because cangrelor was infused intravenously, it was potentially particularly useful for patients for whom oral therapy was not feasible or desirable. Medicines exclusively licensed cangrelor from AstraZeneca in December 2003, and recently, in June 2016, divested itself of the product.

3. Beginning soon after it licensed cangrelor in December 2003, Medicines conducted a number of clinical trials, all seeking to obtain approval from the Food and Drug Administration ("FDA") for expanded uses of the drug, known as New Drug Applications or "NDAs," including:

<u>Trial Name¹</u>	<u>Commenced</u>	<u>Results Published</u>
CHAMPION-PCI	March 2006	November 2009
CHAMPION PLATFORM	October 2006	November 2009
BRIDGE	Q4 2008	Q4 2011
CHAMPION PHOENIX	October 2010	September 2013

4. The CHAMPION PHOENIX trial, which is the subject of this complaint, was designed to support Medicines' NDA for approval of cangrelor in patients with coronary artery

¹ Collectively, CHAMPION-PCI, CHAMPION PLATFORM, and CHAMPION PHOENIX are referred to as the "CHAMPION Trials."

disease undergoing percutaneous coronary intervention (“PCI”). PCI refers to the opening of narrowed blood vessels supplying the heart muscle by a balloon inserted through an artery puncture.

5. In press releases, public filings with the United States Securities and Exchange Commission, and medical symposia, Medicines claimed that the results of its studies on cangrelor evidenced from the CHAMPION PHOENIX clinical trial were statistically significant and showed that the drug had met the trial’s primary endpoints and “demonstrated statistically significant improvement” over its primary competitor, clopidogrel. For example, Medicines claimed in a press release dated October 9, 2013, that the trial “demonstrates that transition from cangrelor to oral clopidogrel 600mg administered immediately after cessation of the cangrelor infusion *significantly reduces thrombotic events at 48 hours compared to clopidogrel alone.*” [Emphasis added].

6. Throughout 2013, the Company issued numerous public statements touting the effectiveness of cangrelor as producing statistically significant improvement over its market competitor, clopidogrel in the CHAMPION PHOENIX clinical trial.

7. On February 10, 2014, the FDA released briefing documents regarding Medicines’ NDA review for cangrelor ahead of the scheduled review by the Cardiovascular and Renal Drugs Advisory Committee. The FDA’s briefing documents reported that cangrelor *did not* show superiority to clopidogrel and, moreover, the clinical trials sponsored by Medicines were inappropriately designed and administered. The briefing document included harsh language by FDA Medical Team Reviewer Dr. Thomas Marciniak, stating: “the CHAMPION trials were conducted unethically. We can refuse approval of cangrelor based on that fact alone.”

8. On February 12, 2014, Medicines issued a press release announcing that NASDAQ had halted trading of the Company's stock while the FDA advisory panel met to discuss the cangrelor NDA. That same day, the FDA advisory panel voted 7-2 to disapprove cangrelor for use in preventing blood clots during heart procedures.

9. These revelations led to a securities fraud action against the Company, Medicines' CEO and Board Member Clive Meanwell, and two other Medicines executives (Chief Financial Officer, Treasurer and Director Glenn P. Sblendorio and the Senior Vice President, General Counsel, and Secretary Paul M. Antinori) captioned *Serr v. The Medicines Company*, No. 2:14-cv-01149 (D.N.J.), which exposed the Company to, *inter alia*, millions of dollars in liability, negative press, and substantial litigation costs. Ultimately, the *Serr* action was settled for a cumulative payment to the class of \$4.25 million. (ECF No. 58).

10. In 2014, Plaintiff, Haverhill Retirement System, which has continuously held shares of Medicines common stock since May 3, 2011, became concerned with the manner in which Medicines was being managed, based in large part on the February 2014 revelations and disclosures by the FDA. The poor management of the CHAMPION PHOENIX trial and the misstatements to investors concerning the anticipated trial results signaled inadequate oversight by the Board – oversight that would have prevented such corporate trauma.

11. Accordingly, on July 21, 2014, Plaintiff used the “tools at hand” and made a request of Medicines pursuant to Section 220 of the Delaware General Corporation Law for books and records with, *inter alia*, a goal of determining whether a majority of the then Board of Directors had the requisite independence and disinterest to fairly and in good faith act upon a shareholder demand to take remedial action. (Plaintiff's July 21, 2014 Section 220 Document Demand is attached as Exhibit A).

12. Plaintiff's counsel received from Defendants, under a vigorously negotiated Confidentiality Agreement, almost 1,000 pages primarily consisting of Board and committee minutes and presentations by which the Board and Board committees were informed about Medicines' clinical trial practices, policies, and procedures. Based upon a review of these documents, Haverhill and its counsel determined that a majority of the then-current directors appeared to possess the requisite independence and disinterest to impartially review a shareholder demand.

13. Accordingly, on November 25, 2014, Haverhill, through its counsel, sent a letter to the Board of Medicines (the "Demand" or "Demand Letter," attached as Exhibit B), demanding that the Board "take legal and equitable action to: (i) require the culpable officers and directors to indemnify the Company for all costs incurred from the securities fraud class action; (ii) require the culpable officers and directors to indemnify the Company for all costs incurred from any past, present, or future internal investigation by Medicines into its internal controls, policies, and procedures; (iii) clawback all compensation and benefits paid to the culpable officers and directors who breached their fiduciary duties to Medicines; and (iv) put forward for shareholder vote, resolutions for amendments to the Company's By-Laws or Articles of Incorporation that will effectively strengthen the Company's internal governance controls to detect and prevent future violations of the federal securities laws, and to strengthen the Company's internal policies and procedures regarding Medicines' drug trials."

14. In response to Haverhill's Demand, on February 4, 2015, Medicines created the Demand Committee, comprised of Defendants Savage and Spigelman (defined below), to oversee an investigation into the issues raised by Haverhill's Demand, and to make a recommendation to the full Board for action with respect to such issues. The Demand

Committee retained the law firm of Skadden, Arps, Slate, Meagher & Flom LLP to provide legal representation.

15. Haverhill's counsel and the Demand Committee's counsel spoke frequently, and Haverhill's counsel proposed various persons to interview and documents to be reviewed by the Demand Committee. On March 26, 2015, counsel had a face-to-face meeting that included Haverhill's suggestion for corporate governance reform that would obviate a similar incident to the CHAMPION PHOENIX clinical trial mismanagement.

16. On December 17, 2015, Counsel for the Demand Committee advised Haverhill's Counsel that, at the conclusion of its investigation, the Demand Committee recommended that it would not be in the best interests of Medicines and its shareholders to commence litigation as demanded. After its review of the Demand Committee's investigation, the full Board declined to bring the claims set forth in Haverhill's Demand. Accordingly, Defendants denied Haverhill's Demand.

JURISDICTION AND VENUE

17. This derivative action is brought pursuant to Rule 23.1 of the Federal Rules of Civil Procedure. This Court has jurisdiction under 28 U.S.C. §1332(a)(1). Plaintiff is a citizen of the Commonwealth of Massachusetts, as set forth in Paragraph 19 below, and Plaintiff and Defendants are citizens of different states and the matter in controversy exceeds \$75,000, exclusive of interests and costs. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

18. Venue is proper in the District of New Jersey because Nominal Defendant Medicines is headquartered in this District and many of the acts and transactions giving rise to the violations of law complained of herein, including the improper conduct by Defendants and

the preparation and dissemination to the investing public of false and misleading information, occurred in this District.

THE PARTIES

19. ***Plaintiff Haverhill Retirement System*** (“Haverhill”) is a contributory retirement system for public employees in Massachusetts, established under Chapter 32 of the Massachusetts General Laws. Haverhill is, and at all relevant times was, a stockholder of Medicines. Plaintiff purchased its first shares of Medicines common stock on May 3, 2011, and has held Medicines shares continuously since that date. Plaintiff has agreed to hold some shares of Medicines until the conclusion of this litigation.

20. ***Nominal Defendant The Medicines Company*** is a Delaware corporation with its principal place of business at 8 Sylvan Way, Parsippany, New Jersey 07054. Medicines is a publicly owned company whose common shares are traded on the Nasdaq Stock Exchange under the symbol “MDCO.”

21. ***Defendant William W. Crouse*** (“Crouse”) has served as a Director of the Company since 2003 through the present. Crouse is also the Chair of the Compensation Committee, and a member of the Nominating and Corporate Governance Committee. Upon information and belief, Defendant Crouse is a citizen of the State of Florida.

22. ***Defendant Alexander J. Denner, Ph.D*** (“Denner”) has served as a Director of the Company since February 2016 through the present. Denner is also a member of the Nominating and Corporate Governance Committee. Upon information and belief, Defendant Denner is a citizen of the State of Connecticut.

23. **Defendant Frederic N. Eshelman, Pharm.D** (“Eshelman”) has served as a Director of the Company since 2015 through the present. Upon information and belief, Defendant Eshelman is a citizen of the State of North Carolina.

24. **Defendant John C. Kelly** (“Kelly”) has served as a Director of the Company since 2011 through the present, and as Lead Director from May to August 2015. Kelly is also the Chairman of the Audit Committee. Upon information and belief, Defendant Kelly is a citizen of the State of Florida.

25. **Defendant Hiroaki Shigeta** (“Shigeta”) has served as a Director of the Company from 2007 through the present, and as Lead Director from May 2010 to September 2012. Shigeta is also a member of the Audit Committee and the Compensation Committee. Upon information and belief, Defendant Shigeta is a citizen of the State of California.

26. **Defendant Melvin K. Spigelman, M.D.** (“Spigelman”) has served as a Director of the Company since 2005 through the present. Spigelman is also a member of the Audit Committee. Spigelman is also one of the two directors on the Demand Committee. Upon information and belief, Defendant Spigelman is a citizen of the State of New York.

27. **Defendant Robert G. Savage** (“Savage”) has formerly served as a Director of the Company from April 2003 to August 2016. Savage was also one of the two directors on the Demand Committee appointed by the full Board to investigate Plaintiff’s Demand. Upon information and belief, Defendant Savage is a citizen of the State of Florida.

28. Defendants Crouse, Denner, Eshelman, Kelly, Shigeta, Spigelman, and Savage are collectively referred to as the “Individual Defendants.” Defendants Crouse, Denner, Eshelman, Kelly, Shigeta, and Spigelman are six of the ten directors who sit on the current Board of Directors.

DEFENDANTS' FIDUCIARY DUTIES

29. By reason of their positions as directors of The Medicines Company, and by virtue of their ability to control the business and corporate affairs of the Company, each Individual Defendant owed and owes Medicines and its shareholders fiduciary obligations of trust, loyalty, good faith, and candor, and were and are required to use their utmost ability to control and manage the Company in a lawful, fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Medicines and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

30. Each of the Individual Defendants owed and owes to Medicines and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

31. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of the Company, and was at all times acting within the course and scope of such agency.

32. By virtue of their fiduciary duties of loyalty, good faith, trust, and candor, each Individual Defendant was required to, among other things:

- a. exercise good faith to ensure that Medicines' affairs were conducted in an efficient, business-like manner;
- b. exercise good faith to ensure that the Company was operated in a diligent, honest, and prudent manner and that it complied with all applicable federal and state laws, rules, regulations, and requirements, and all contractual obligations, including acting only within the scope of its legal authority;
- c. when put on notice of problems with the Company's business practices

and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence; and

- d. remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith.

33. The Individual Defendants who were and are members of the Board committees assumed the responsibility to carry out the functions of their committees.

SUBSTANTIVE ALLEGATIONS

34. Medicines provides medical solutions, through biopharmaceutical products for patients in acute and intensive care hospitals worldwide. Until its recent divestiture of the drug, one of the Company's products was cangrelor, a new platelet P2Y₁₂ receptor inhibitor studied for use for patients undergoing percutaneous coronary intervention ("PCI") for the treatment of angina or acute coronary syndromes. Cangrelor was designed to prevent blood clots in patients undergoing stenting procedures.

35. Medicines had projected that, if approved by the FDA for use in patients undergoing PCI interventions, cangrelor could generate up to \$450 million in peak sales.

36. Specifically, Medicines had sought FDA approval for cangrelor for two separate indications: (1) for the reduction of thrombotic cardiovascular events including stent thrombosis in patients undergoing PCI; and (2) for the maintenance of antiplatelet therapy in patients with acute coronary syndromes or patients with stents who have discontinued antiplatelet therapy because they are awaiting surgery and are at high risk for thrombotic events.

37. During calendar year 2013, the Individual Defendants caused the Company to issue several false and misleading statements regarding cangrelor and its prospects for FDA approval of its New Drug Application ("NDA") for cangrelor. Several examples of these misstatements are referenced in Plaintiff's November 25, 2014 Demand.

a. The Company's March 1, 2013 statement "[i]n January 2013, we announced that data analysis of our Phase 3 CHAMPION PHOENIX clinical trial revealed that the protocol defined primary composite efficacy endpoint of death, myocardial infarction, ischemia driven revascularization and stent thrombosis at 48 hours had been met, *as cangrelor demonstrated statistically significant improvement for this endpoint compared to clopidogrel.* [Emphasis added].

b. The Company's April 24, 2013 statement "[w]e also advanced our portfolio of acute and intensive care hospital medicines, *as we recently . . . reported the positive results of the Phase 3 cangrelor PHOENIX trial.*" [Emphasis added].

c. The Company's November 5, 2013 statement: "Cangrelor Clinical Trial Program. In September 2013, we presented and published a pooled analysis of our CHAMPION clinical trial program, which consisted of three Phase 3 clinical trials of cangrelor (CHAMPION-PCI, CHAMPION PLATFORM and CHAMPION PHOENIX). In the trials, we compared IV cangrelor to either oral clopidogrel or placebo for prevention of thrombotic (clotting) complications during and after PCI. *The totality of evidence in the approximately 25,000 patients undergoing PCI that participated in the trials demonstrated that cangrelor significantly reduced the odds of the primary composite endpoint of death, myocardial infarction (MI), ischemia-driven revascularization (DR) or stent thrombosis (ST) at 48 hours after randomization.* . . . The new pharmacodynamics studies add to clinical data from the CHAMPION PHOENIX trial that *demonstrated that transition from cangrelor infusion significantly*

reduces thrombotic events at 48 hours compared to clopidogrel alone. The FDA accepted the filing of the NDA for cangrelor in the United States in July 2013 and we expect to file an MAA in the European Union in the fourth quarter of 2013.” [Emphasis added].

38. Ultimately, on February 10, 2014, the FDA released briefing documents regarding Medicines’ NDA review for cangrelor. These briefing documents reported scathing comments by Dr. Thomas Marciniak, the FDA’s Medical Team Leader for the NDA review, to the effect that cangrelor did not show superiority to clopidogrel and that the clinical trials sponsored by Medicines were unethically and inappropriately administered. The briefing documents provided that “the CHAMPION trials were conducted unethically. We can refuse approval of cangrelor based on that fact alone.”

39. Specifically, Dr. Marciniak concluded that the “CHAMPION trials do not show superiority or noninferiority of a cangrelor regiment to clopidogrel or to standard of care,” and further concluded that clopidogrel was delayed inappropriately in all three trials. He noted that “the greater the delay in administering clopidogrel, the better cangrelor looked for efficacy.” He also determined that clopidogrel was “never consistently administered early enough, such that [the FDA] cannot even conclude that cangrelor is noninferior to clopidogrel,” calling the delay in administration of clopidogrel “very disturbing.”²

40. Two days later, Medicines issued a press release announcing that NASDAQ had halted trading of the Company’s stock while the FDA advisory panel met to discuss the cangrelor NDA. That same day, the FDA advisory panel voted 7-2 not to approve cangrelor to prevent blood clots during heart procedures.

² <http://www.medscape.com/viewarticle/820412>.

41. As a result of these disclosures, the price of Medicines common stock has fallen precipitously.

42. The actions and inaction of the Individual Defendants have caused Medicines to sustain millions of dollars in damages and expenses, as well as substantial reputational harm. These damages include the litigation costs and expenses, as well as the \$4.25 million settlement of the *Serr* securities fraud action, the potential loss of future revenue for Medicines, and the loss of the Company's reputation in the business and investing community and among the public at large.

43. The Individual Defendants' decision to reject Plaintiff's November 25, 2014 Demand, based upon the investigation of the Demand Committee, is wrongful and not entitled to business judgment protection, because the entire process was flawed:

a. The two-member Demand Committee possessed authority to only recommend to the Board a decision as to whether or not to proceed with an action against the culpable directors. The full Board, including the culpable directors named in the November 2014 Demand, made the ultimate decision whether to sue themselves – a decision that is hardly independent and is riddled with self-interest.

b. From time to time the Plaintiff made suggestions to counsel for the Demand Committee of persons with knowledge who should be interviewed and critical documents that should be reviewed. The Demand Committee refused to even advise the Plaintiff whether it accepted any of those suggestions. Not providing this fundamental information requested of counsel demonstrates that even the most basic elements of legitimacy were not respected by the Demand Committee.

c. The Demand Committee's investigation utterly fails to meet the requisite standard of thoroughness, good faith and reasonableness required by Delaware law. That all directors, even those who participated in the wrongdoing regarding the administration and public reporting of results of the CHAMPION PHOENIX clinical trial, had to ratify the decision to not sue themselves shows that rejection of Plaintiff's Demand was a foregone conclusion, not entitled to protection under the business judgment rule.

FIRST CAUSE OF ACTION

For Breaches of Their Fiduciary Duties of Loyalty and Good Faith (Against All Defendants)

44. Plaintiff incorporates by reference each of the foregoing allegations.

45. Defendants are fiduciaries of Medicines and of all of its public shareholders and owe to them the duty to conduct the business of the Company loyally and in good faith. The Board of Directors has a duty to respond to a shareholder demand in good faith and in a reasonable manner, and make a decision that is in the best interest of the Company and not that of any particular director.

46. Defendants' denial of Plaintiff's Demand is a breach of their fiduciary duties.

47. As a result of Defendants' breach, Medicines is being made to bear the entire financial burden of all the fees, expenses, and settlements incurred as a result of the unlawful activities engaged in by Medicines' employees, and Medicines has suffered and will continue to suffer considerable damage. Defendants' refusal to initiate litigation on behalf of the Company against the wrongdoers is wrongful and not made in good faith.

48. By reason of the foregoing, all Defendants have breached their fiduciary obligations to Medicines and its shareholders.

49. Medicines and its shareholders have been injured by reason of these breaches. Plaintiff, as a stockholder of Medicines, seeks damages and other relief for the Company as set forth below.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff demands judgment on behalf of Medicines as follows:

(A) An order that the Board's determination to deny the Demand is not taken in good faith and is wrongful;

(B) An order that the Company was harmed as a result of the Individual Defendants' misconduct;

(C) Authorizing Plaintiff to pursue a derivative complaint on behalf of the Company against all of the Individual Defendants whose disloyalty to the Company caused or contributed to the harm to the Company.

(D) Awarding Plaintiff, on behalf of Nominal Defendant, Medicines, damages in an amount to compensate for the losses, harm, cost and expense incurred by Medicines as a result of the Individual Defendants' misconduct;

(E) Directing the Individual Defendants to establish and maintain an effective corporate governance and compliance program to ensure that Medicines' directors, officers and employees engage in effective oversight over the Company's clinical trial management and reporting to prevent similar harm to Medicines in the future; and

(F) Awarding Plaintiff the costs and disbursements of this Action, including reasonable attorneys', accountants', and experts' fees, costs and expenses.

DATED: March 9, 2017

**SCOTT+SCOTT,
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s/ Judith S. Scolnick

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CERTIFICATE OF SERVICE

A true and correct copy of the foregoing document was served on counsel this 9th day of March 2017, via email and regular U.S. Mail, as follows:

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